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April 24, 2000

Docket Management Branch (HFA-305)  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Docket No. 97N-0436 - - FDA Draft Study Report: Feasibility of  
Appropriate Methods of Informing Customers of the Contents of  
Bottled Water**

Dear Sir or Madam:

The National Soft Drink Association (NSDA) is pleased to submit comments regarding the U.S. Food and Drug Administration's (FDA) draft study report addressing the feasibility of appropriate methods to inform customers of the content of bottled water as requested by the Agency in the Federal Register of February 22, 2000 (65 FR 8718).

NSDA is the national trade organization of the United States soft drink industry. NSDA's members produce more than 95% of all soft drinks consumed annually in the United States. In addition, the vast majority of the soft drink licensors who manufacture concentrates and/or syrups from which soft drinks are made belong to the Association. Further, a growing number of our member companies are involved in the production and distribution of bottled waters. It is on behalf of these members that NSDA submits these comments.

I. Agreement with FDA's Conclusions

We agree fully with the conclusion of the draft study report that FDA should not require the label of a bottled water to set forth all of the information that EPA requires each community water system to provide annually to its customers in the form of a Consumer Confidence Report ("CCR"). FDA correctly concluded that requiring all such information to appear on a bottled water label is neither practicable nor economically feasible.

We also agree with FDA's conclusion that the least costly method of providing such information to consumers of bottled water would be to send that information to consumers who request it by calling a telephone number or writing to an address that appears on the label.

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## II. Problems of the Proposed "Combination Approach"

FDA's draft study report also discusses what the agency refers to as a "combination approach," which would consist of the bottled water producer's providing some CCR information on the label and the rest in response to telephone or written requests from consumers. FDA requests advocates of the combination approach to provide the agency with "information on which pieces of CCR-type information should go on the label and which should be available through company contact." 65 Fed. Reg. at 8721. The report states that "many comments advocated placing certain individual pieces of information, such as information on the source of the water, information about the suitability of the water for consumption by immunocompromised individuals, or fluoride levels, on the label, while making other CCR-type information available to customers through contact with the company." Id.

### A. General Shortcoming of the Combination Approach

We submit that the combination approach would neither effectively nor clearly communicate information about the contents of bottled water. Rather, the information presented on the label would appear out of context, separated from the remainder of the CCR information, which the consumer would need in order to understand the full meaning and significance of the information presented on the label. For example, given the limited amount of available label space, any label statement concerning the suitability of a bottled water for consumption by immunocompromised individuals would be too brief and too lacking in detail to explain the relative risk associated with drinking that bottled water as compared to other risks such persons may encounter. Similarly, a label statement about the source of water, e.g., a river that is polluted in certain places, could be misleading if separated from a more detailed explanation of the exact location on the river from which the water is taken, e.g., upstream of the source of pollution, and of the extent of treatment to which the water had been subjected. As a result, the combination approach could confuse and even alarm consumers.

### B. Absence of Justification for Requiring Label Declaration of Particular Information

Furthermore, with respect to each of the particular categories of information that FDA specifies in the request for comments, FDA has already determined what label statements should or should not be required. FDA previously considered essentially the same issues in the rulemaking processes that resulted in the bottled water regulation, 21 C.F.R. § 165.110, and the regulation establishing general principles for nutrient content claims, 21 C.F.R. § 101.13. The agency therefore should not devote any of its limited resources reconsidering these issues.

### 1. Source Information

FDA considered what information about source must be disclosed on the label when it established the standards of identity for various types of bottled water in §165.110(a), such as, e.g., “spring water” and “well water.” FDA considered the same subject in establishing § 165.110(a)(3)(ii), which requires the label of a bottled water made using water from a community water system to bear a statement to that effect on the principal display panel, except that purified or sterilized water is expressly exempted from this requirement. The agency concluded that additional label disclosures about the source of such highly treated bottled water are neither material nor necessary.

We submit that there is no purpose in FDA’s revisiting this issue in the context of determining how the agency should require bottled water producers to communicate information such as that contained in a CCR. Rather, the agency should require the disclosure of further information about the source not on the label itself, but only in the CCR information that the bottled water producer sends to consumers who call a telephone number or write to an address that appears on the label. Even if the agency concludes that bottled water labels should disclose additional information about source, purified and sterilized water should remain exempt from any such requirement, as they are under current § 165.110(a)(3)(ii). Furthermore, to require disclosure of the source on a purified or sterilized water would be misleading to a consumer because the chemical composition of the finished water is demonstrably different than the composition of the source. Such information is irrelevant to public health.

### 2. Information About Risk of Bottled Water for Immunocompromised Individuals

With respect to the suitability of bottled water for consumption by immunocompromised individuals, the principal concern is the presence of potentially pathogenic microorganisms. FDA considered what information about microbiological contamination must be disclosed on the label in the course of establishing § 165.110(c). That subsection states that if any bottled water fails to satisfy the requirements of § 165.110(b) with respect to microbiological, physical, chemical, and radiological quality, such bottled water must bear on its label a statement that it is of substandard quality. To that end, the label must bear the statement required by § 130.14(a), “Below Standard in Quality Good Food – Not High Grade,” except that, depending on what is appropriate under the circumstances, the label must bear, instead of or in addition to the general § 130.14(a) statement, one or more of the following:

1. “Contains Excessive Bacteria,”
2. “Excessively Turbid,” “Abnormal Color,” and/or “Abnormal Odor,”

3. "Contains Excessive Chemical Substances" or "Contains Excessive \_\_\_\_\_," with the blank filled with the name of the contaminant exceeding the maximum permitted level; or
4. "Excessively Radioactive."

As a result, pursuant to § 165.110(c), the label of a bottled water that does not satisfy the microbiological quality requirements of § 165.110(b) is already required to disclose that fact. We submit that there is no purpose in FDA's revisiting this issue in the present context, given that the current regulation requires such a label disclosure for a product of substandard quality and given that consumers will be able to obtain detailed information regarding microbiological content by calling a telephone number or writing to an address included on the label.

Requiring further detailed information on the label of bottled water would not only oversimplify a complex issue, it would set an ill-advised precedent for other foods and beverages. The potential risk of microbiological contamination to immunocompromised individuals is certainly not limited to bottled water. To single out bottled water, which poses a comparably low risk relative to pathogenic microorganisms, would be misleading, and would undoubtedly raise labeling issues with other foods and beverages.

### 3. Information About Fluoride Level

With respect to the level of fluoride in bottled water, FDA has previously concluded that label statements characterizing the amount of added fluoride are inappropriate and should not be permitted. Under § 101.13(q)(8), which is a subsection of the regulation establishing general principles for nutrient content claims, the terms "fluoridated," "fluoride added," or "with added fluoride" may be used on the label of a bottled water that contains added fluoride. However, in the preamble to that regulation, FDA stated as follows:

FDA believes that while the presence of fluoride in bottled water is of interest to consumers and its declaration should not be prohibited, the agency does not wish to encourage unnecessary addition of fluoride to bottled water. The agency is concerned that if terms like "good source of fluoride" or "high in fluoride" were permitted, they might encourage such additions.

58 Fed. Reg. 2302, 2314 (Jan. 6, 1993). As a result, label statements characterizing the level of added fluoride in a bottled water are not permitted. Given the agency's expressed desire not to encourage unnecessary fluoride fortification, we believe that FDA would also disapprove of claims characterizing the level of naturally occurring fluoride on products that do not contain added fluoride. In light of this history, we submit that

there is no purpose in FDA's revisiting this issue in the present context. Consumers will be able to obtain information regarding fluoride level by calling a telephone number or writing to an address included on the label of a bottled water.

### III. Conclusion

In summary, we agree with FDA's conclusion that the agency should not require bottled water producers to disclose CCR information on their labels. In addition, we urge FDA to reject the combination approach and to require instead that bottled water producers provide CCR information only in response to requests from interested consumers.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mike Redman", written over a horizontal line.

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## FIRST CLASS

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